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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,212	01/04/2002	Steven M. Ruben	1488.0360000	3494
22195	7590	04/30/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/035,212

Applicant(s)

RUBEN ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 2-5 are canceled. Claims 6-19 are added. Claims 1, 6-19 are pending.
2. Response to restriction requirement filed 01/20/2004 is acknowledged. Applicant elected, with traverse, claims 6-19. Applicant argues that all groups should be examined because the claims are drawn to product, method of making and method of using. However, this argument is not well taken because there never have been any claims drawn to a product. Further, claims drawn to the groups II-IV are canceled by applicant. The restriction requirement is still deemed proper and is therefore made FINAL.

In regard to claim 1, as applicant specifically elected claims 6-19, claim 1 (which, effectively, is a reiteration of new claim 13) is withdrawn from consideration. Cancellation of claim 1 is requested.

### ***Information Disclosure Statement***

3. Applicants' Information Disclosure Statements filed 08/05/2002 and 08/28/2002 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

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***Abstract***

4. The abstract of the invention is not descriptive. The abstract does not reflect the elected invention. A new abstract is required which is clearly indicative of the invention to which the elected claims are directed.

***Sequence Listing***

5. The Sequence Listing was approved by STIC for matters of form.

***Claim Rejections - 35 USC § 102 and 103.***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103<sup>©</sup> and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 6,7,9,10,13,14,16,17 are rejected under 35 U.S.C. 102(b) as anticipated by WO 98/16642. The reference teaches KGF-2 and uses thereof. KGF-2 (SEQ ID NO.2, see Fig. 1 in the reference) has the same sequence as instantly claimed KGF-2, and, consequently, reads on a polypeptide comprising residues 63-208 of instant SEQ ID No. 2). The reference teaches that KGF-2 can be used for treatment of variety of disorders, including inflammatory conditions such as inflammatory bowel disease (pages 51-52).

8. Claims 6,7,9-14,16-19 are rejected under 35 U.S.C. 102(b) as anticipated by Han et al (Database Caplus, DN 134:13722; American Journal of Physiology (2000), 279(5, Pt. 1), G1011-G1022) or Jimenez et al. (Database Caplus, DN 133:12799, 2000), or Miceli et al (Database Caplus, DN 131:282007; Journal of Pharmacology and Experimental Therapeutics (1999), 290(1), 464-471). The references teach that

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KGF-2 can be used for treatment of inflammatory bowel diseases if administered before or during the disease. See abstracts.

9. Claims 8,11,12,15,18,19 are rejected under 35 U.S.C. 103(a) as obvious over WO 98/16642.

If there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. Although the prior art does not teach all potential inflammatory diseases and particular methods of administration, it would be conventional and within the skill of the art to identify inflammatory disorders susceptible to the treatment, as well as protocols of treatment.

***Conclusion.***

10. No claims are allowed

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

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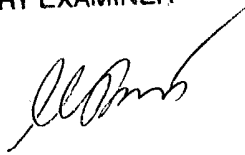
unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

April 26, 2004

mlb

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written below the printed name.